

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Certifier R. LEDESMA

**Joint Meeting of the Nonprescription Drugs Advisory Committee and the  
Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committees:* Nonprescription Drugs Advisory Committee (NDAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC).

*General Function of the Committees:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 13, 2005, from 8 a.m. to 5 p.m., and January 14, 2005, from 8 a.m. to 3 p.m.

*Location:* Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* Cathy A. Groupe, or Hilda F. Scharen, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail [GroupeC@cderr.fda.gov](mailto:GroupeC@cderr.fda.gov) or [scharenh@cderr.fda.gov](mailto:scharenh@cderr.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 and oc04296

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3014512536. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On both days, the committees will consider the safety and efficacy of new drug application (NDA) 21-213, proposing over-the-counter (OTC) use of MEVACOR (lovastatin), 20 milligrams a day, Merck & Co., Inc., to help lower LDL “bad” cholesterol, which may prevent a first heart attack. The background material will become available no later than the day before the meeting and will be posted under the NDAC or the EMDAC Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> (click on the year 2005 and scroll down to NDAC or EMDAC).

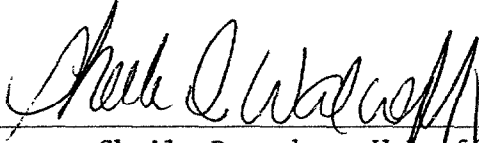
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 6, 2005. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:30 a.m. on January 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated: Dec 1, 2004  
December 1, 2004.



Sheila Dearybury Walcott,  
Associate Commissioner for External Relations.

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